

**PATENT/Docket No. 6231.N CN1**

Appl. No. 09/500,246

Filing Date: February 8, 2000

Reply to Office action of January 15, 2005

**AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claims 1-25. (Canceled)

26. (Currently amended) An implant composition, suitable for implantation in an animal body by injection, comprising:

(a) a first component comprising a biologically active composition comprising melengestrol acetate or a combination of melengestrol acetate and trenbolone acetate, or a combination of melengestrol acetate, and trenbolone acetate, and estradiol, contained in a first delivery vehicle capable of immediately releasing said biologically active composition upon implantation in a animal body and which is selected from the group consisting of solid compressed tablets, and solid compressed pellets, and mixtures thereof, comprising a disintegrating agent which causes the tablet or the pellet to rapidly break down when in body fluids, and wherein said biologically active composition is in fine or micronized particle sizes, or in freeze dried form, or mixtures thereof; and

(b) a second component comprising the same biologically active composition as in the first component, (a) contained in a second delivery vehicle capable of releasing said biologically active composition on a sustained release basis upon implantation in an animal body and which is selected from the group consisting of solid compressed tablets, and solid compressed pellets, and mixtures thereof, wherein said second delivery vehicle further comprises biodegradable solid substances, conventional tablet/pellet ingredients, conventional tablet/pellet ingredients coated with a polymeric membrane to control release, gel-forming excipients, non-biodegradable polymers, biodegradable polymers, lipidic excipients, and mixtures thereof, and wherein said biologically active composition in the second delivery vehicle has large particle sizes.

27. (Previously presented) The implant composition of Claim 26 wherein the first delivery vehicle comprises solid compressed tablets or solid compressed pellets or mixtures thereof

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containing a disintegrating agent and wherein the second vehicle comprises solid compressed tablets or solid compressed pellets or mixtures thereof not containing a disintegrating agent.

28. (Previously presented) The implant composition of Claim 27, wherein said disintegrating agent is selected from the group consisting of sodium crosscarmellose, microcrystalline cellulose, sodium carboxymethyl-cellulose, alginic acid, starch, potassium polacrilin, colloidal silicon dioxide, crospovidone, guar gum, magnesium aluminum silicate, methyl cellulose, powdered cellulose, pregelatinized starch, sodium starch glycolate and sodium alginate and mixtures thereof.

29-31. (Canceled).

32. (Previously presented) The implant composition of Claim 26, wherein the melengestrol acetate is contained in each delivery vehicle in an amount of from about 5 to about 200 mg per delivery vehicle.

33. (Previously presented) The implant composition of Claim 26 wherein either component (a) or component (b) or both further comprises one or more of the following materials: standard granulating aids, lubricants, diluents, binders and glidants, magnesium stearate, stearic acid, colloidal silicon dioxide, talc, titanium dioxide, magnesium, calcium and aluminum salts, lactose, cyclodextrins and derivatives thereof, starches, povidone, high molecular weight polyethylene glycols and derivatives thereof, bioerodible polymers and co-polymers, polystearates, carboxymethyl cellulose, cellulose, N,N-diethylamine acetate, polyvinyl alcohol, hydroxypropyl methyl cellulose, other biologically active or inactive substances or pharmaceutically active substances.

34-35. (Canceled).

36. (Currently amended) A method for delivering the same biologically active material to an animal body in both a rapid release and sustained release form comprising the steps of:

(1) providing an implant comprising:

(a) a first component comprising a biologically active composition comprising melengestrol acetate, a combination of melengestrol acetate and trenbolone acetate, or a combination of melengestrol acetate, trenbolone acetate and estradiol, contained in a first delivery vehicle capable of immediately releasing said biologically active composition upon implantation in

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an animal body and which is selected from the group consisting of solid compressed tablets, solid compressed pellets, and mixtures thereof, comprising a disintegrating agent which causes the tablet or pellet to rapidly break down when in body fluids, and wherein said biologically active composition is in fine or micronized particle sizes, or in freeze dried form, or mixtures thereof; and

(b) a second component comprising the same biologically active composition as in the first component, (a) contained in a second delivery vehicle capable of releasing said biologically active composition on a sustained basis upon implantation in an animal body and which is selected from the group consisting of solid compressed tablets, and solid compressed pellets, and mixtures thereof, wherein said second delivery vehicle further comprises biodegradable solid substances, conventional tablet/pellet ingredients, conventional tablet/pellet ingredients coated with a polymeric membrane to control release, gel-forming excipients, non-biodegradable polymers, biodegradable polymers, lipidic excipients, and mixtures thereof; and wherein said biologically active composition in the second delivery vehicle has large particle sizes.

(2) injecting said implant into the animal body.

37. (Previously presented) The method of Claim 36 wherein the first delivery vehicle comprises solid compressed tablets or solid compressed pellets or mixtures thereof containing a disintegrating agent and wherein the second vehicle comprises solid compressed tablets or solid compressed pellets or mixtures thereof not containing a disintegrating agent.

38. (Previously presented) The method of Claim 37, wherein said disintegrating agent is selected from the group consisting of sodium crosscarmellose, microcrystalline cellulose, sodium carboxymethyl-cellulose, alginic acid, starch, potassium polarcilin, colloidal silicon dioxide, crospovidone, guar gum, magnesium aluminum silicate, methyl cellulose, powdered cellulose, pregelatinized starch, sodium starch glycolate and sodium alginate and mixtures thereof.

39-41. (Canceled).

42. (Previously presented) The method of Claim 36, wherein the melengestrol acetate is contained in each delivery vehicle in an amount of from about 5 to about 200 mg per delivery vehicle.

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43. (Previously presented) The method of Claim 36, wherein said animal is selected from the group consisting of cows, horses, sheep, swine, dogs, and cats.
44. (Previously presented) The method of Claim 43, wherein said animal is a heifer.
45. (Previously presented) The method of Claim 36 wherein said implanting step is selected from the group consisting of subcutaneous, intramuscular, intraperitoneal, and intracranial injections.
46. (Previously presented) The method of Claim 45 wherein said animal is a heifer and said implanting step comprises subcutaneous injection in the posterior of the ear of said heifer.
47. (Previously presented) The method of Claim 36 wherein step (2) comprises a single injection.
48. (Previously presented) The implant composition of Claim 26 wherein the preparation of said first delivery vehicle and said second delivery vehicle comprises the steps of 1) wet, dry, or fluid bed granulation or extrusion/spheronization; 2) particle screening and sizing; and 3) tablet or pellet compression.
49. (Previously presented) The method of claim 36 wherein the preparation of said first delivery vehicle and said second delivery vehicle comprises the steps of 1) wet, dry, or fluid bed granulation or extrusion/spheronization; 2) particle screening and sizing; and 3) tablet or pellet compression.
50. (Previously presented) The implant composition of Claim 26 wherein said second delivery vehicle is selected from the group consisting of matrix-type systems based on gel-forming excipients, matrix-type systems based on non-biodegradable polymers, membrane-type systems based on non-biodegradable polymers, matrix type systems based on biodegradable polymers, matrix type systems based on lipidic excipients, and combinations thereof.
51. (New) An implant composition of Claim 26, wherein said biologically active composition in the second delivery vehicle has particle sizes larger than the particle sizes of the biologically active composition in the first delivery vehicle.
52. (New) A method of Claim 36, wherein said biologically active composition in the second delivery vehicle has particle sizes larger than the particle sizes of the biologically active composition in the first delivery vehicle.

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